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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,226	01/20/2004	Philip C. Gevas	17118-056002 / 2835B	2197

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FISH & RICHARDSON, PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
UNGAR, SUSAN NMN	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/762,226	GEVAS ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *June 27, 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1 and 3-7* is/are pending in the application.

4a) Of the above claim(s) *6 and 7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1 and 3-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/27/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 27, 2007 is acknowledged and has been entered. Claim 1 has been amended. An action on the RCE follows.

2 Claims 1, 3-5 are pending and currently under examination.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

4. Claims 1 and 3-5 are rejected under 35 USC 112, first paragraph, as lacking an adequate written description in the specification and failing to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method for treatment of gastrointestinal tumors comprising administering an anti-G-17 immunogenic composition in an amount sufficient to induce an anti-gastrin-17 antibody titer to neutralize gastrin-17 and glycine-extended gastrin-17.

The specification teaches a single immunogen, pGlu-Gly-Pro-Trp-Leu-Glu-Glu-Glu-Glu-peptide spacer-carrier protein, which raises antibodies which bind both the amidated and glycine-extended forms of G17 (p. 5). The antibody titers raised by the anti-G17 immunogen is in excess of those required to neutralize serum G17 resulting in high serum levels of uncomplexed antibodies which are

free to bind to G17-Gly (p. 10) and successfully treat an in vivo model of colon carcinoma.

Gura (Science, 1997, 278:1041-1042) teaches that researchers face the problem of sifting through potential anticancer agents to find ones promising enough to make human clinical trials worthwhile and teach that since formal screening began in 1955, many thousands of drugs have shown activity in either cell or animal models but that only 39 have actually been shown to be useful for chemotherapy (p. 1041, see first and second para). Further, Kaiser (Science, 2006, 313, 1370) specifically teaches that 90% of tumor drugs fail in patients; see col 3, 2nd to last para). Because of the known unpredictability of the art, in the absence of experimental evidence in an appropriate animal model, with data commensurate in scope with the invention claimed, no one skilled in the art would accept the assertion that the claimed method would function as claimed with any G-17 immunogen other than that exemplified based only upon the demonstration that the exemplified immunogen functions as claimed.

Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that [a] written description of an invention involving a chemical genus, like a description of a chemical species, >requires a precise definition, such as by structure, formula, [or] chemical name,= of the claimed subject matter sufficient to distinguish it from other materials.≅ Id. At 1567, 43 USPQ2d at 1405. The court also stated that

> a generic statement such as vertebrate insulin cDNA or mammalian insulin cDNA without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Id. At 1568, 43 USPQ2d at 1406. The court concluded that naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. AA description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that Athe written description requirement can be met by >show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between

function and structure, or some combination of such characteristics. Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims such as those at issue here. A disclosure that does not adequately describe a product itself logically cannot adequately describe a method of using that product.

Thus, the instant specification may provide an adequate written description of the G-17 immunogen that is effective to raise antibodies that bind to and neutralize G-17 and glycine-extended G-17, wherein the titer raised is in excess of that required to neutralize serum G17 resulting in high serum levels of uncomplexed antibodies which are free to bind to G17-Gly effective to treat gastrointestinal tumors, per Lilly by structurally describing a representative number of said immunogens that will function as claimed or by describing structural features common to the members of the genus, which features constitute a substantial portion of the genus. Alternatively, per Enzo, the specification can show that the claimed invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

In this case, the specification does not describe the G-17 immunogen that is effective to raise antibodies that bind to and neutralize G-17 and glycine-extended G-17, wherein the titer raised is in excess of that required to neutralize serum G17 resulting in high serum levels of uncomplexed antibodies which are free to bind to G17-Gly effective to treat gastrointestinal tumors required to practice the method of the claims in a manner that satisfies either the Lilly or Enzo standards. The

specification does not provide the complete structure of G-17 immunogen that is effective to raise antibodies that bind to and neutralize G-17 and glycine-extended G-17, wherein the titer raised is in excess of that required to neutralize serum G17 resulting in high serum levels of uncomplexed antibodies which are free to bind to G17-Gly effective to treat gastrointestinal tumors, nor does the specification provide any partial structure of such G-17 immunogen that is effective to raise antibodies that bind to and neutralize G-17 and glycine-extended G-17, wherein the titer raised is in excess of that required to neutralize serum G17 resulting in high serum levels of uncomplexed antibodies which are free to bind to G17-Gly effective to treat gastrointestinal tumors, nor any physical or chemical characteristics of the G-17 immunogen that is effective to raise antibodies that bind to and neutralize G-17 and glycine-extended G-17, wherein the titer raised is in excess of that required to neutralize serum G17 resulting in high serum levels of uncomplexed antibodies which are free to bind to G17-Gly effective to treat gastrointestinal tumors nor any functional characteristics coupled with a known or disclosed correlation between structure and function, other than a single immunogen, pGlu-Gly-Pro-Trp-Leu-Glu-Glu-Glu-Glu-peptide spacer-carrier protein.

Although the specification discloses a single G-17 immunogen that is effective to raise antibodies that bind to and neutralize G-17 and glycine-extended G-17, wherein the titer raised is in excess of that required to neutralize serum G17 resulting in high serum levels of uncomplexed antibodies which are free to bind to G17-Gly effective to treat gastrointestinal tumors, this does not provide a description of the broadly claimed immunogen that would satisfy the standard set out in Enzo.

The specification also fails to describe the G-17 immunogen that is effective to raise antibodies that bind to and neutralize G-17 and glycine-extended G-17, wherein the titer raised is in excess of that required to neutralize serum G17 resulting in high serum levels of uncomplexed antibodies which are free to bind to G17-Gly effective to treat gastrointestinal tumors by the test set out in Lilly. The specification describes only a single G-17 immunogen that is effective to raise antibodies that bind to and neutralize G-17 and glycine-extended G-17, wherein the titer raised is in excess of that required to neutralize serum G17 resulting in high serum levels of uncomplexed antibodies which are free to bind to G17-Gly effective to treat gastrointestinal tumors. Therefore, it necessarily fails to describe a representative number of such species. In addition, the specification also does not describe structural features common to the members of the genus, which features constitute a substantial portion of the genus.

Thus, the specification does not provide an adequate written description of the G-17 immunogen that is effective to raise antibodies that bind to and neutralize G-17 and glycine-extended G-17, wherein the titer raised is in excess of that required to neutralize serum G17 resulting in high serum levels of uncomplexed antibodies which are free to bind to G17-Gly effective to treat gastrointestinal tumors that will function as claimed that is required to practice the claimed invention or reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the broadly claimed invention. Since the specification fails to adequately describe or reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the broadly claimed invention immunogen that will function as claimed, it also fails to adequately describe the

claimed method or reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

. Claim Rejections - 35 USC 112

5. Claims 1 and 3-5 are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of wherein "the gastrointestinal tumor expresses glycine-extended gastrin-17" has no clear support in the specification and the claims as originally filed.

Applicant points to support for the newly added claim amendment in original claim 2. The argument has been considered but has not been found persuasive because original claim 2 recites only "The method of claim 1, wherein the immunogen induces anti-G17 antibodies of an effective titer in the immunized mammal which bind and neutralize amidated and glycine-extended gastrin- 17" but does not provide support for the gastrointestinal tumor expresses glycine-extended gastrin-17.

Applicant points to support for the newly added claim amendment at page 5, lines 4-10 and 17-21. The argument has been considered but has not been found persuasive because a review of page 5 reveals support only for

> "The present invention provides immunological methods for the treatment of gastrin-dependent tumors which comprise the active or passive immunization of a patient with anti-G17 immunogen or antibodies against gastrin 17 hormone in order to control the patient's glycine-extended and amidated gastrin 17 levels. **By inducing anti-gastrin 17 antibodies in a human patient, the hormone gastrin 17 and the prohormone progastrin G17-G!y are neutralized in vivo, so as to inhibit their physiological effects. In particular, the neutralization of G17 and the precursor G17-**

> **Gly prevents the binding of these peptides to their physiological receptors, thereby inhibiting the growth of the tumor cells.** The anti-G17 immunogens, comprise fragments of the N-terminal amino acids of G17 conjugated to an immunogenic carrier such as Diphtheria toxoid (DT), by a spacer peptide, and raise antibodies which bind both the amidated and glycine-extended forms of G17.
> In one embodiment of the invention, the method of immunization against amidated or glycine-extended G17 comprises active immunization, wherein a patient is immunized with an immunogen of the invention. **The immunogen stimulates the production of antibodies against amidated and glycine-extended G17 in the immunized patient, inducing sufficient antibody titers to neutralize and inhibit the physiological effects of amidated and glycine-extended G17 so as to limit the cancer-trophic hormone levels produced by the patient.** The physiological neutralization of progastin G17-Gly hormone by the anti-G17 antibodies produced in the patient"

but does not provide support for the gastrointestinal tumor expresses glycine-extended gastrin-17, but rather only teaches that the antibodies neutralize the physiological effects of the hormones so as to limit the cancer-trophic hormone levels produced by the patients. Nowhere is there any indication that the hormones are expressed by the tumor.

Applicant points to support for the newly added claim amendment at page 9, lines 9-14. The argument has been considered but has not been found persuasive because a review of page 9, lines 9-14 reveals support only for

> In the present invention, a serum sample from the patient having a gastrointestinal cancer can be assayed to determine the level of G17-Gly in the patient's blood. An effective dosage ranging from 0.001 to 2mg of the immunogenic composition is administered to the patient for the treatment of the gastrointestinal cancer. **The effective dosage of the immunogenic composition should be capable of eliciting an immune response in a patient of effective levels of antibody titer against both human gastrin**

> **17 and the G17-Gly within 1-3 months after immunization.** Following the immunization of a patient, the antibody titer levels against amidated or glycine-extended G17 are monitored from a sample of blood taken from the patient, and booster immunizations should be given as required

but does not provide support for the gastrointestinal tumor expresses glycine-extended gastrin-17, but rather only teaches guidance drawn to antibody titers and determining level of G17-Gly in patient's blood. Nowhere is there any indication that the hormones are expressed by the tumor.

Finally Applicant points to support for the newly added claim amendment at page 10, lines 9-13. The argument has been considered but has not been found persuasive because a review of page 10, lines 9-13 reveals support only for

> The antibody titers raised by the anti-G17 immunogens are in excess of those required to neutralize serum G17 resulting in high serum levels of uncomplexed antibodies which are free to bind to G17-Gly. Thus, the 'free' serum-associated antibodies would be available to neutralize cell-associated G17 peptides in well-vascularized areas of the tumors.

but does not provide support for the gastrointestinal tumor expresses glycine-extended gastrin-17, but rather only teaches guidance drawn to levels of immunogens required to neutralize serum G17. Nowhere is there any indication that the hormones are expressed by the tumor.

The subject matter claimed in claims 1 and 3-5 broadens the scope of the invention as originally disclosed in the specification.

6. Claim 1 and 3-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 3-5 are indefinite in the recitation "wherein: the gastrointestinal tumor expresses glycine-extended gastrin-17". The claims are

confusing because the art recognizes that glycine-extended gastrin-17 is not "expressed" by any cells but rather is a product of the processing of preprogastrin and therefore a post-translational product of the preproprotein expressed in cells. Therefore, the metes and bounds of claimed patent protection cannot be determined.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 3-5 are rejected under 35 USC 102(e) as being anticipated by US Patent No. 5,785,970, of record, as evidenced by Blackmore et al, (Int. J. Cancer, 1994,57:385-391) of record, as evidenced by Watson et al (Cancer Res, 1996, 56:880-886, IDS reference) as evidenced by Baldwin and Shulkes (Gut, 1998, 42;581-584).

The claims are drawn to a method for treatment of gastrointestinal tumors comprising administering to a mammal a therapeutically effective amount of an anti-G17 immunogenic composition, wherein the gastrointestinal tumor expresses glycine-extended gastrin 17, sufficient to induce an anti-gastrin-17 antibody titer to neutralize gastrin-17 and glycine-extended gastrin-17 (claim 1), wherein the gastrointestinal tumors contain CCK-B receptors (claim 3), wherein the gastrointestinal tumors are colorectal adencarcinomas (claim 4), wherein the mammal is a human (claim 5).

Watson et al specifically teach that immunization of mammals with gastroimmune, a peptide 100% identical to the therapeutic of US Patent No. 5,785,970, raises antibodies that neutralize both gastrin 17 and glycine-extended gastrin 17.

Blackmore et al teach that cell line HCT-116 is a colon adenocarcinoma cell line (see abstract) and that antagonists to gastrin/CCK receptor, also known as CCK-B receptor, inhibit gastrin dependent growth of the cells. Clearly demonstrating that the cell line comprises CCK-B receptors.

Baldwin and Shulkes specifically provide convincing evidence that cell line HCT116 produces progastrin derived peptides (p. 582, col 2) and specifically teach that prograstrin derived peptides include glycine extended gastrin 17 and gastrin 17, wherein the reference specifically teaches the conventional and well understood processing of progastrin to gastrin 17 which includes the production of the glycine extended gastrin-17 peptide intermediate (see Figure 1, p. 582).

Given the indefinite nature of the claim language drawn to "gastronintestinal tumor expresses glycine-extended gastrin-17" (see above), it will be assumed for examination purposes that any tumor that comprises glycine-extended gastrin-17, "expresses" the hormone

US Patent No. 5,785,970 claims a method of treating a gastro-intestinal disorder, comprising administering to a mammal a therapeutically effective amount of an anti-G 17 immunogen comprising a fragment of the N-terminal amino acid sequence of heptadecagastrin (claim 1), wherein the mammal is a human (para 4 of the Description of the invention), wherein said immunogen is capable of eliciting a sufficient titer of antibodies in the patient which selectively bind and neutralize the patients own G 17 (claim 4) wherein the peptide consists essentially of pGlu-Gly-

Pro-Trp-Leu-Glu-Glu-Glu-Glu (claim 11). It is noted that inherent in the administration of an immunogen is a composition comprising said immunogen. Further, the reference exemplifies the treatment of mammals comprising HCT-116 colon adenocarcinoma xenograft tumors which are treated by administering said immunogen (see Example 6).

The successful method of the prior art comprises the same method steps as claimed in the instant invention, that is, administering the same therapeutic as disclosed in the instant specification (a therapeutic that will neutralize gastrin-17 and glycine-extended gastrin), to the same population, that is mammal suffering from gastronintestinal tumor, thus, the claimed method is anticipated because it will inherently lead to the successful production of an immune response to both gastrin-17 and glycine-extended gastrin-17 that is in excess of that required to bind to gastrin 17 alone, that will neutralize both hormones in a mammal suffering from a tumor that inherently expresses CCK-B receptors and produces progastrin derived peptides. See Ex parte Novitski 26 USPQ 1389 (BPAI 1993).

Although the reference does not specifically teach that the HCT-116 cells "express" glycine-extended gastrin-17, given that HCT-116 cells inherently express progastrin-derived peptides, wherein glycine-extended gastrin-17 is a naturally produced intermediate in the processing of progastrin, given that the immunogen used in the prior art reference inherently neutralizes gastrin-17 and glycine-extended gastrin-17, it appears that the progastrin-derived peptides that are successfully neutralized in the successful method of the prior art reference are both gastrin-17 and glycine-extended gastrin-17. Thus, the claimed method appears to be the same as the prior art method. The office does not have the facilities for examining and comparing applicant's method with the method of the prior art in

order to establish that the method of the prior art does not possess the same material structural and functional characteristics of the claimed method. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed method is functionally
different than that taught by the prior art and to establish patentable differences. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

Some of Applicant's arguments drawn to the rejection of claims 1 and 4-5 in the paper mailed12/27/06 are relevant to the instant rejection.

Applicant argues that US 5,785,970 does not disclose the treatment of gastrointestinal tumors that express glycine-extended gastrin-17.

The argument has been considered but has not been found persuasive for the reasons set forth above..

Applicant argues that US Patent 5,785,970 does not disclose a method in which an amount of anti-G17 immunogen that is administered must be sufficient to neutralize gastrin 17 and glycine-extended gastrin-17 which would be in excess of the amount required just to inhibit gastrin-17. The argument has been considered but has not been found persuasive because Applicant is arguing limitations not recited in the claims as currently constituted. Further, it is noted that although the claims recite the limitation that the amount administered is sufficient to induce an anti-gastrin-17 antibody titer to neutralize gastrin-17 and glycine-extended gastrin-17, given that the immunogen of the prior art reference inherently produces antibodies that neutralize both hormones, both hormones would clearly be neutralized. It is noted, that the extent of neutralization required for either or both of the hormones is not disclosed in either the specification or the claims.

Applicant argues that since not all gastrointestinal tumor express glycine-extended 17, the population of patients treated is different. The argument has been considered but has not been found persuasive because given that the HCT-116 tumors inherently express progestin derived peptides which are clearly neutralized by the treatment of the prior art reference, given that the production of glycine-extended gastrin-17 is a convention part of the processing of progastrin, it appears that the prior art method is the same as the instantly claimed method, and in the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed method is functionally different than that taught by the prior art and to establish patentable differences.

Applicant cites case law teaching Examiner the requirements for rejection under 35 USC 102 and inherency. The recitation of the case law is acknowledged but since Applicant does not present arguments drawn to the case law, it is unclear what relevance the citations have to the instant rejection.

Applicant argues that all of the claims require that the amount of the immunogenic composition be sufficient to generate antibodies that neutralize both gastrin-17 and glycine-extended gastrin-17 and not all anti-Gly17 compositions are capable of eliciting antibodies to both gastrin-17 and glycine extended gastrin 17.

The argument has been considered but is not found persuasive for the reasons set forth above.

Applicant argues that the prior art reference does not teach all of the limitations of the instant claims. The argument has been considered but has not been found persuasive because, for the reasons set forth above, it appears that the prior art method is the same as the instantly claimed method, and in the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed

method is functionally different than that taught by the prior art and to establish patentable differences.

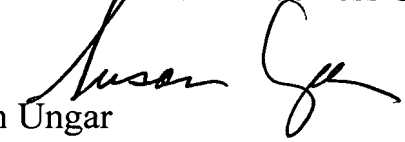
Applicant reiterates arguments that the claims recite that the amount of immunogen required to neutralize the effects of G17 and glycine-extended gastrin-17 is an amount capable of generating an antibody titer in excess of that needed to inhibit gastrin-17 alone. The argument has been considered but has not been found persuasive for the reasons set forth above.

9. No claims allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley, can be reached at 571-272-0898. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Susan Ungar
Primary Patent Examiner
August 26, 2007